ROSS LAW OFFICES, P.C.

Civil Litigation Concentrating in Recovery for Negligence and Wrongful Death

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Howard S. Ross, Civil Litigator
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September 12, 2018

Stryker Orthopaedics
2825 Airview Boulevard
Kalamazoo, MI 49002
Attn: Legal Department

Howmedica Osteonics/Stryker
325 Corporate Drive
Mahwah, NJ 07430
Attn: Legal Department

Re: Brenda Healy v. Howmedica Osteonics, Corp., et. al.
Norfolk Superior Court C.A. #1882CV00807

Dear Sir/Madam:

Pursuant to the Massachusetts Long Arm Statute, you are hereby served with the enclosed Summons and Complaint in the above-entitled lawsuit.

Your failure to file an Answer in Court within 20 days may result in a default judgment entered against you. Please immediately fax this letter and the enclosed documents to your professional liability insurer and ask your insurer(s) to contact me.

Thank you for your attention to this matter.

Very truly yours,

Howard S. Ross

HSR/md
Enclosure

VIA CERTIFIED MAIL RETURN RECEIPT REQUESTED
AND EXPRESS OVERNIGHT MAIL

(TO PLAINTIFF'S ATTORNEY: PLEASE CIRCLE TYPE OF ACTION INVOLVED: TORT - MOTOR VEHICLE TORT - CONTRACT - EQUITABLE RELIEF - OTHER)

COMMONWEALTH OF MASSACHUSETTS

NORFOLK, ss.

SUPERIOR COURT
CIVIL ACTION
NO. 1882CV00807

Brenda Healy, *Plaintiff(s)*

v.

Howmedica, et. al., *Defendant(s)*

SUMMONS

To the above-named Defendant:

You are hereby summoned and required to serve upon Howard Ross, plaintiff's attorney, whose address is 18 E. Chestnut St, Sharon, MA 02067, an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You are also required to file your answer to the complaint in the office of the Clerk of this court at Dedham either before service upon the plaintiff's attorney or within a reasonable time thereafter.

Unless otherwise provided by Rule 13(a), your answer must state as a counterclaim any claim which you may have against the plaintiff which arises out of the transaction or occurrence that is the subject matter of the plaintiff's claim or you will thereafter be barred from making such claim in any other action.

WITNESS, JUDITH FABRICANT, Esquire, at Norfolk the 12th day of September, in the year of our Lord two thousand and eighteen

Walter F. Timilty, *Clerk.*

NOTES:
1. This summons is issued pursuant to Rules 4 of the Massachusetts Rules of Civil Procedure.
2. When more than one defendant is involved, the names of all such defendants should appear in the caption. If a separate summons is used for each such defendant, each should be addressed to the particular defendant.

F-33

COMMONWEALTH OF MASSACHUSETTS

NORFOLK, ss

SUPERIOR COURT
CIVIL ACTION NO.:

BRENDA HEALY
Plaintiff

vs.

CORIN GROUP, PLC,
CORIN USA LIMITED, INC.,
HOWMEDICA OSTEONICS CORP. and
DANIEL C. SNYDER, M.D.
Defendants.

PLAINTIFF CLAIM
TRIAL BY JURY

COMPLAINT

FACTUAL ALLEGATIONS

1. The plaintiff Brenda Healy resides in Walpole, Norfolk County, Massachusetts.

2. The defendant Corin Group PLC is a foreign corporation with a principal place of business at The Corinium Centre, Cirencester, GL7 1YJ, United Kingdom, but does business in Massachusetts.

3. The defendant Corin USA Limited, Inc. is a foreign corporation with a principal place of business at 5670 W. Cypress Street, Suite C, Tampa, Florida 33607, but does business in Massachusetts.

4. The defendant Howmedica Osteonics Corporation is a foreign corporation with a principal place of business at 325 Corporate Drive, Mahwah, New Jersey 07430, but does business in Massachusetts.

5. The defendant Daniel C. Snyder, M.D., is an orthopedic surgeon with a principal place of business at Newton Wellesley Orthopaedic Associates, 2000 Washington St # 341, Newton, MA 02462.

6. On September 16, 2010, Brenda Healy underwent total right hip arthroplasty at Newton Wellesley Hospital in Newton, MA performed by Daniel C. Snyder, M.D. During this surgery, the following devices that were designed, developed, tested, distributed, and sold by the Howmedica Osteonics Corp., were inserted into Brenda Healy's body:

(a) Restoration ADM Anatomic Dual Mobility Acetabular Cup (Ref: 1235-2-541; LOT: G2912034); and

(b) Restoration ADM X3 insert for Restoration ADM cup (REF: 1236-2-854; LOT: 34023001).

Additionally, the following devices that were designed, developed, tested, and sold by the Corin defendants and sold and distributed to defendant Snyder by Howmedica Osteonics Corp. were inserted into Brenda Healy's body:

(c) Modular Head (12/14 Eurocone), 28 mm short offset – 3.5 mm (CoCr) (LOT 177658); and

(d) Minihip Hip Stem, Size 4, Standard Neck (REF: 580.0004; LOT 164210)

(all hereinafter referred to as the "hip system").

7. On September 17, 2015, Brenda Healy submitted to explant surgery (a right hip revision total hip arthroplasty) at Massachusetts General Hospital in Boston performed by Young-Min Kwon, M.D. in which the hip system manufactured, sold, and distributed by the defendants had to be surgically removed. Her diagnoses included "aseptic loosening of right hip acetabular cup, metallosis."

The operative report indicates, inter alia, that Brenda "underwent a right total hip arthroplasty on September 16, 2010, with a Corin mini-hip system, as well as Stryker ADM cup. The patient had been experiencing increasing pain that had not improved with conservative measures. Laboratory studies show an ESR of 38, CRP of 16.4, as well as an aspiration which showed a cell count of 203 and 34% TMN….. The patient had an elevated chromium level performed on June 24, 2015, with chromium of 2.0, cobalt of 3, suggestive for corrosion and metallosis….. It was noted that the patient had developed severe metallosis around the hip abductors with roughly 30% abductor necrosis. Additionally, there was a collection of metal debris within the pericapsular fluid…. Once assessing the tissue around the acetabulum, it was noted that there was metallosis-type debris around the acetabular cup…."

The plaintiff suffered additional damage to her hip and surrounding tissues as reflected in the MGH record.

8. These claims are timely under the common law of Massachusetts and M.G.L. Chapter 93A because Brenda Healy did not discover and should not have discovered that her injuries were due to the defendants' actions until she underwent her revision surgery on September 17, 2015; or at the very earliest, when she learned of elevated chromium and cobalt levels on June 24, 2015.

9. If these Cormet or Stryker products are classified as a Class III medical device which received premarket approval ("PMA") from the FDA, that will not provide a defense to the plaintiff's claims reasons including, inter alia, the following:

a. As one condition of approval, each product marketed and sold by Defendants was required to be manufactured in exact compliance with the standards and specifications approved by the FDA.

b. The components may have been approved by the FDA, must be composed of cobalt and chromium in compliance with ASTM F75 (which describes standard specifications for "Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants") and ISO 5832-4 (which describes the international standardization for metal surgical implants using "Cobalt-chromium-molybdenum casting alloy").

c. The surfaces of the cup and cap components that rub together must—as per FDA approval—be manufactured according to a radial clearance design, meaning that the cap is a predefined amount smaller than the cup, leaving an area of "clearance" between the surfaces in order to reduce abrasion.

d. The surfaces of the cup and cap that rub against each other are required to be highly polished, with less than 0.05 micrometers R_a (average roughness), meaning that, on average, the measurements of peaks and valleys on a surface must be less than 0.05 micrometers. A micrometer is one-ten-thousandth of a centimeter (*i.e.*, there are ten thousand micrometers in a centimeter). In other words, if the surfaces of the cup and cap were examined microscopically, the difference between the highest peaks and the lowest valleys on the surface must

not, on average, be 0.05 micrometers or greater. This requirement is a measurement of surface smoothness. If the surfaces of the cup and cap that abrade against each other are rougher than this requirement dictates, they will wear at a faster rate and will cause much larger levels of metallic ion shedding than anticipated in Defendants' PMA data.

e. The sphericity of the cup and cap components must be controlled to less than 10 micrometers. Sphericity is a measurement of the "departure from round," which is a type of error that can occur during the manufacturing process. The sphericity requirement dictates that the cup and cap components of the Hip system may not deviate from perfect roundness by more than 10 micrometers (*i.e.*, by more than one-thousandth of a centimeter), because components that deviate from a "perfectly round" shape by more than 10 micrometers will have uneven and greater-than-anticipated wear rates. In other words, if the cup and cap components deviate from perfect roundness by more than one-thousandth of a centimeter, they will not rub together evenly, causing certain portions of their surfaces to bear a burden of wear and abrasion greater than that which they were designed to withstand. This increased wear and abrasion will cause these surfaces to deteriorate faster than anticipated in Defendants' PMA data, causing a greater-than-anticipated level of metallic ion release.

f. As approved by the FDA, the hip system products were required to be "high carbon," meaning that all of its surfaces must contain 0.20% to 0.35% carbon. Surfaces that are "high carbon" are harder and better able to withstand wear and abrasion without releasing metallic particles from their surfaces into the

surrounding tissues. Surfaces that are not "high carbon" are less resistant to wear and abrasion, and thus more likely to release metallic particles from their surfaces under ordinary conditions.

g. The coating on the cup and cap components must be a combination of hydroxyapatite and unalloyed titanium. The titanium must meet the ASTM F1044 standard for static shear, the ASTM F1147 standard for static tensile, the ASTM F1160 standard for shear fatigue tests, and the ASTM F1978 standard for abrasion resistance, as well as FDA guidance standards for chemical analysis, surface roughness, and coating thickness. A titanium coating of this nature will ensure that the Hip system is able to withstand the stresses of ordinary use without releasing dangerous levels of metallic ions into the patient's body.

h. The hydroxyapatite coating must meet the ASTM F1185 standard for composition of surgical implants, the ASTM F1147 standard for static tensile, and the FDA guidance standards for chemical analysis, crystallinity, and coating thickness. As with the titanium coating, a coating of hydroxyapatite meeting these standards will be sufficiently resilient under normal condition to prevent the release of excessive levels of metallic ions.

i. The foregoing specifications and standards are collectively referred to herein as the "Approved Design Standards."

j. As part of the FDA PMA process, representatives of Corin Group PLC and Corin USA Limited admitted to the FDA that, although it was possible for low levels of cobalt and chromium ions to be released into a patient's surrounding tissues, those

levels could be kept to a level that would be insignificant to a patient's health by "maintaining quality control of device production."

k. Defendants use hip stimulator tests to ensure that each Hip system they manufacture performs in accordance with the testing data provided to the FDA in the PMA process and complies with the Approved Design Standards set forth above.

l. Defendants' hip stimulator tests use a synovial fluid "substitute" to lubricate the metal bearings before the device is subjected to numerous simulations of normal hip articulation. Synovial fluid is the natural fluid produced by the human body to lubricate the various joints, such as the hip joint, to reduce friction when surfaces rub together in the process of joint articulation.

m. In simple terms, the testing procedure is to (1) lubricate the cup and cap components with an artificial lubricant that takes the place of synovial fluid; (2) mechanically "walk" the hip through numerous repetitions of stimulated hip movement, causing the cup and cap to rub together like a normal hip joint would; and (3) to examine the surfaces of the cup and cap to ensure that they did not incur wear greater than that predicted in Defendants' PMA testing data.

n. However, research has shown that lubrication equivalent to that used in Defendants' hip stimulation tests does not always occur within the human hip once the Hip system is implanted. The amount of a patient's natural synovial fluid is often far less than the amount of artificial lubricant used in the hip stimulation tests. In fact, it is often this lack of synovial fluid which contributes to joint damage necessitating the hip resurfacing procedure in the first place.

o. Therefore, in actual use, where the artificial lubricant used in the hip stimulator tests is absent and synovial fluid is often minimal, there are many times when the metal surfaces actually abrade with little or no synovial fluid to lubricate them, resulting in far more stress being placed upon the cup and cap surfaces than would be identified in Defendants' quality control testing. At these times, the cup and cap grind together much more harshly than they do in the well-lubricated hip stimulator tests.

p. This difference is particularly significant because the hip stimulator tests—which Defendants use to test whether the materials and components used in the manufacture of each Hip system comply with the Approved Design Standards—effectively place the cup and cap components on "water skis," creating an unrealistically thick layer of fluid that separates the metal surfaces and reduces the abrasion between them in the testing environment.

q. This unrealistic testing procedure makes little difference for Hip systems that are manufactured in accordance with the Approved Design Standards mandated by the FDA, because the Approved Design Standards require the cup and cap components to be made of materials capable of withstanding such unlubricated abrasion with little to no metallic particle shedding. However, for individual Hip systems which, due to a flaw in the manufacturing process, do not meet the Approved Design Standards, this testing flaw allows nonconforming products to pass inspection unnoticed.

r. In essence, the hip stimulator tests Defendants used were inadequate because they are insufficiently realistic. The tests allow devices that do not conform to the Approved Design Standards to be marketed and sold as thought they do.

COUNT I. BRENDA HEALY V. CORIN GROUP, PLC., CORIN USA LIMITED, INC. AND HOWMEDICA OSTEONICS CORP.)

10. Plaintiff repeat and reaver the allegations of Paragraphs 1-9 herein.

11. This cause of action is based on the contention that defendants violated federal statutes and regulations. Plaintiff is pursuing parallel state common law claims based upon defendants' violations of applicable federal regulations. Accordingly, this cause of action is not preempted under 21 U.S.C. §360K.

12. The Hip system received approval from the FDA PMA process on July 3, 2007, subject to numerous conditions, including the requirement that every Hip system manufactured by Defendants would adhere strictly to the Approved Design Standards set forth above.

13. These Approved Design Specifications, and other laws together comprise the statutory and regulatory standard of care for the design, manufacture, labeling, marketing, sale, and use of the Hip system.

14. The purpose of the PMA process is to ensure that devices like the Hip system are carefully examined and thoroughly understood before being marketed to the public in order to provide reasonable assurance of their safety and effectiveness.

15. In light of this purpose, both (1) the general regulations promulgated by the FDA that apply to all Class III medical devices, and (2) all device-specific requirements imposed pursuant to the PMA process for the Hip system were specifically enacted to protect

those patients purchasing and receiving the Hip system. In other words, FDA's regulations and device-specific requirements were designed to protect a class of individuals of which Brenda Healy is a member.

16. In subjecting the Hip system to the PMA procedure, the FDA sought to prevent the physical, mental, emotional, psychological, and financial injuries that would foreseeably be caused by the substandard or nonconforming design, manufacture, or labeling of hip-resurfacing devices like the Hip system. The injuries Brenda Healy has sustained are therefore injuries of the type the FDA and Congress sought to prevent by subjecting Class III medical devices to the PMA process.

17. The Hip system Brenda Healy received was not manufactured in strict compliance with the Approved Design Standards set forth above. The Approved Design Standards describe the only acceptable end result of the manufacturing process for the Hip system, and the Hip system Brenda Healy received does not match that end result. Accordingly, the device Brenda Healy received violates the conditions of the FDA's approval and the general regulations applicable to Class III medical devices. Specifically, Brenda Healy's Hip system suffers from one or more of the following manufacturing defects:

a. The chromium-cobalt composition of the cup and cap components of Brenda Healy's hip system does not adhere to ASTM F75 and ISO 5832-4, resulting in a Hip system inadequately resistant to wear and metallic ion release;

b. The cup and cap components of Brenda Healy's Hip system were manufactured with a radial clearance different from that which the FDA approved, causing certain aspects of the components to degrade at a greater than anticipated rate;

c. The surfaces of the cup and cap were insufficiently polished, resulting in excessively rough surfaces of 0.05 micrometers Ra or greater. This caused abnormally great abrasion during joint articulation and the release of cobalt and chromium ions into Brenda Healy's surrounding tissues at a rate far greater than would have resulted if the surfaces had complied with the Approved Design Standards;

d. The cup and cap components in Brenda Healy's Hip system deviated from perfect roundness by more than 10 micrometers, causing the surfaces to wear unevenly and allowing the release of dangerous amounts of cobalt and chromium particles into Brenda Healy's surrounding tissues;

e. The cup and cap components of Brenda Healy's Hip system do not contain the requisite 0.20% to 0.35% carbon, resulting in weaker surfaces that are less able to withstand wear and abrasion than they would be had they been manufactured according to the Approved Design Specifications;

f. The titanium coating on the cup and cap components of Brenda Healy's Hip system does not meet the ASTM F1044 standard for static shear, the ASTM F1147 standard for static tensile, the ASTM F1160 standard for shear fatigue tests, the ASTM F1978 standard for abrasion resistance, or the FDA guidance standards for chemical analysis, surface roughness, and coating thickness, resulting in a coating that offers inadequate protection against wear and abrasion and allows dangerous levels of cobalt and chromium ions to be released from the cup and cap surfaces; and

g. The hydroxyapatite coating on the cup and cap components of Brenda Healy's Hip system does not meet the ASTM F1185 standard for composition of surgical implants, the ASTM F1147 standard for static tensile, or the FDA guidance standards for chemical analysis, crystallinity, and coating thickness, resulting in a coating that offers inadequate protection against wear and abrasion and allows dangerous levels of cobalt and chromium ions to be released from the cup and cap surfaces.

18. Pursuant to 21 C.F.R. § 814.9, virtually all device-specific information reviewed by the FDA in the PMA process is confidential as a matter of federal law. Consequently, further discovery will be necessary before Brenda Healy may identify all device-specific requirements that Defendants failed to meet in manufacturing her hip system. See *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010) ("[D]istrict courts must keep in mind that much of the product-specific information about manufacturing needed to investigate such claim fully is kept confidential by federal law. Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim.").

19. Defendants violated the conditions of the FDA's approval by failing to adhere to the Good Manufacturing Practices ("GMPs") promulgated by the FDA which are mandatory requirements for all Class III medical devices.

20. Harm, damages, and the injuries sustained by plaintiff were the direct and proximate result of the carelessness and negligence of the defendants as follows:

a. Defendants negligently designed, developed, assembled, manufactured, inspected, tested, marketed, advertised, sold and distributed the hip system

in that they knew or should have known they were violating the following federal regulations:

i. Defendants violated 21 C.F.R. §820.30 by failing to establish and maintain procedures to control the design of the Hip system. As a result, the Hip system Brenda Healy received did not comply with the Approved Design Standards as set forth above, causing the injuries set forth herein.

ii. Defendants violated 21 C.F.R. § 820.70 by failing to adhere to federally mandated production and process controls. Had Defendants adhered to the requirements of § 820.70, the Hip system Brenda Healy received would have complied with the Approved Design Standards, and Brenda Healy would not have suffered the injuries set forth herein.

iii. Defendants violated 21 C.F.R. § 820.86 by failing to identify acceptance criteria for the conformance or nonconformance of the Hip system throughout the manufacturing, packaging, labeling, installation, and servicing of the product. As a result, the Hip system that Brenda Healy received was not identified as nonconforming and was allowed to be distributed and sold despite its failure to adhere to the Approved Design Standards. Brenda Healy suffered the injuries described

herein due to this failure to identify acceptance criteria for Brenda Healy's Hip system.

iv. Defendants violated 21 C.F.R. § 820.90 by failing to establish and maintain procedures to identify, document, evaluate, segregate and dispose of products like the Hip system that Brenda Healy received that do not conform to the Approved Design Standards. If Defendants had complied with § 820.90, the device Brenda Healy received would have been identified as nonconforming and would never have been offered for sale. As a result of Defendants' failure, Brenda Healy received a nonconforming Hip system and was injured as set forth herein.

v. Defendants violated the Manufacturer Reporting Requirements contained in 21 C.F.R. §§ 803.50, 803.52, 803.53, 803.56, and 803.58 by failing to report adverse events of injuries similar to those suffered by Brenda Healy. Had Defendants reported these adverse events as required by law, Brenda Healy and her doctors would have been better able to make an informed decision regarding the hip system and would have been able to identify the cause of Brenda Healy's symptoms much sooner, thereby limiting the damages she suffered. Instead Brenda Healy was allowed to receive a device that did not comply with

the Approved Design Standards, causing (and exacerbating) Brenda Healy's injuries as set forth herein.

vi. By reason of their use of unrealistic lubrication, Defendants' hip simulator tests are insufficient and inadequate to identify products that fail to conform to the Approved Design Standards.

vii. Brenda Healy's hip system was improperly tested using an unrealistic hip stimulation test that failed to identify that her hip system was manufactured in a way that violated one or more of the Approved Design Standards. This inadequate quality control and testing procedure violated 21 C.F.R. § 820.30, which requires Defendants to establish and maintain procedures to control the design of a Class III medical device and to appropriately test such a device to ensure that all design requirements are met.

viii. This insufficient and unrealistic device testing procedure also violated 21 C.F.R. § 820.90, which requires Defendants to establish and maintain adequate procedures for identifying, documenting, evaluating, segregating, and disposing of nonconforming products like the hip system that Brenda Healy received. As described above, Defendants' procedures wholly failed to identify that Brenda Healy's device was manufactured in violation of

the Approved Design Standards which were a condition of the FDA's original approval of the hip system, allowing it to pass inspection undocumented and to reach the market despite its manufacturing defects.

ix. As a result of this failure to properly test the hip system, Defendants allowed Brenda Healy to receive a device that did not comply with the Approved Design Standards, which should have been identified and rejected before ever leaving Defendants' manufacturing facilities. Instead, Brenda Healy received a hip system that could not withstand ordinary wear and tear, causing extremely elevated levels of cobalt and chromium ions to be released into her body and causing severe metallosis and tissue damage, which was seen and photographed by her surgeons upon surgical removal the hip components, including the Stryker cup, and causing other medical problems, injuries, and damages as set forth herein.

21. Brenda Healy's damages were directly and proximately caused by microscopic metallic particles of cobalt and chromium that have been released from the metal surface of the cup and cap components of the hip system. Had Defendants manufactured the hip system Brenda Healy received in accordance with the Approved Design Standards, this particle release would not have occurred.

22. Accordingly, the excessive metal ion release was the direct and proximate result of Defendants' violation of the Approved Design Standards and the applicable GMPs. including but not limited to those identified above.

23. These metallic particles then contaminated Brenda Healy's surrounding tissues, causing serious adverse local tissue reactions and other damages and harm, all directly and proximately caused by the greater-than-anticipated metallic ion release resulting from Defendants' violations of the Approved Design Standards and applicable GMPs.

24. As a result of the excessive release of metal ions caused by Defendants' violations of the Approved Design Standards and applicable GMPs, Brenda Healy was caused to undergo a revision procedure. This revision procedure was necessitated by Defendants' failure to adhere to the Approved Design Specifications.

25. As a direct and proximate result of Defendants' violations of the statutory and regulatory standards of care, as embodied in the Approved Design Standards, Brenda Healy has incurred medical expenses that would have been unnecessary but for Defendants' violations; has suffered years of debilitating physical and mental pain and anguish; has been forced to seek out extensive medical treatment; has lost income and suffered a loss of earning capacity; and has been required to undergo additional painful and invasive procedures to address the continuing problems that have resulted from the implantation of the hip system that failed to conform to the Approved Design Standards, the applicable GMPs, and other statutory and regulatory standards of care to which the hip system is subject.

26. Brenda Healy's injuries are such as would not ordinarily have occurred under the circumstances in the absence of a failure by Defendants to fully adhere to the Approved Design Standards, the applicable GMPs, and the other statutory and regulatory standards of care to which the hip system was subject.

27. Defendants expressly and impliedly warranted to plaintiff and to the general public that said product was safe, merchantable and fit for their intended purposes and uses. Defendants breached its warranties because said product was unsafe, not of merchantable quality and unfit for its intended uses and purposes. Plaintiff relied on the warranties made by defendants, and the plaintiff sustained injury as the direct and proximate result of the breaches of warranties by defendants. Due notice has been given to defendants of their breaches of warranty. The breaches of warranty resulted from defendants' non-compliance with the FDCA and the regulations promulgated thereunder in one or more of the following ways:

a. the device was adulterated in violation of 21 U.S.C. §351(h) and 21 CFR Parts 803 and 820, as specified herein;

b. the device was misbranded in violation of 21 U.S.C. §352(t) and 21 CFR Parts 803 and 820, as specified herein.

28. As a direct and proximate result of the negligence and breach of warranty of defendants as set forth herein, the plaintiff was caused to sustain severe and permanent injuries including the injuries specified herein. She has had extensive medical care and will probably require additional future care. Her quality of life has been adversely affected. She does not enjoy life as she did prior to the occurrence.

WHEREFORE, plaintiff prays judgment against defendants, together with interest and costs.

COUNT II: CH. 93 V. CORIN GROUP, PLC., CORIN USA LIMITED, INC. AND HOWMEDICA OSTEONICS CORP.

29. The plaintiff repeats and reavers the allegations of Count I herein.

30. The actions of defendants constituted an unfair and deceptive practice within the meaning of M.G.L. c. 93A as follows:

a. the defendants breached warranties in connection with design, manufacture, development, testing, marketing and sale of its products as set forth herein.

b. the products were defective in that they contained inadequate warnings and instructions, resulting in breach of warranty and set forth herein.

c. the products were defective in that they did not comply with applicable regulations as set forth herein.

31. As a direct and proximate result of the unfair and deceptive practices of defendant as set forth herein, the plaintiff sustained severe injuries as set forth above.

32. On or about February 22, 2016, plaintiff made a written demand for relief pursuant to Chapter 93A which is attached as Exhibit A.

33. In defendants' response of March 17, 2016, defendants failed to grant the requested relief. See Exhibit B.

34. The use or employment of unfair and deceptive practices set forth herein were willful and knowing violations of M.G.L. c. 93A.

35. The defendants' refusal to grant relief upon demand was made in bad faith with knowledge or reason to know that the acts and practices complained of violated Chapter 93A.

WHEREFORE, plaintiff prays that the court grant the following relief against defendant:

a. Find that the conduct of the defendants was a violation of Chapter 93A.

b. Find that the actions of the defendants were a knowing violation of Chapter 93A and/or that their refusal to grant relief upon demand was made in bad faith.

c. Award plaintiff treble damages, costs, and attorneys' fees on her claim.

COUNT III: BRENDA HEALY V. DANIEL C. SNYDER, M.D.

36. The plaintiff, Brenda Healy, repeats and reavers the allegations of the Counts I and II herein.

37. The defendant, Daniel C. Snyder, recommended, distributed, sold, and implanted into plaintiff Brenda Healy the subject hip system.

38. The hip system implanted into Brenda Healy at Newton Wellesley Hospital in Newton, Massachusetts, was not reasonably fit for its intended uses and purposes as set forth herein and was in breach of the Implied Warranty of Merchantability..

39. Defendant Daniel C. Snyder knew, or should have known, when he recommended, formulated, and implanted the hip system into Brenda Healy's right hip that this hip system and its component should not have been used by him.

40. Defendant expressly and implied warranted to plaintiff and to the general public that said products were safe, merchantable and fit for their intended purposes and uses. Defendant breached the warranties implied by law because said products were unsafe, not of merchantable quality, and unfit for their intended uses and purposes. Plaintiff relied on the warranties made by defendant, and plaintiff sustained injury as the direct and proximate result of the breaches of warranties by defendant. The breaches of warranty resulted from:

a. the device was adulterated in violation of 21 U.S.C. §351(h) and 21 CFR Parts 803 and 820, as specified herein;

b. the device was misbranded in violation of 21 U.S.C. §352(t) and 21 CFR Parts 803 and 820, as specified herein.

41. As a direct and proximate result of the breach of warranty and conduct of defendant Daniel C. Snyder as set forth herein, the plaintiff was caused to sustain severe and permanent injuries including the injuries specified herein. She has required extensive medical care and will probably require additional future care. Her quality of life has been adversely affected. She does not enjoy life as she did prior to the occurrence.

WHEREFORE, plaintiff prays judgment against defendant, together with interest and costs.

WHEREFORE, plaintiff prays judgment against all defendants, together with interest, costs, and double or treble damages, and attorney's fees, as provided by law.

PLAINTIFF CLAIMS TRIAL BY JURY.

Respectfully submitted,

The Plaintiff, Brenda Healy,
By her Attorney

Howard S. Ross, Esq.
BBO #429960
Ross Law Offices, P.C.
18 East Chestnut Street
Sharon, MA 02067
(781) 793-0330
(781) 793-0335 Fax
Email: info@rosslawofficespc.com

DATED: June 18, 2018

EXHIBIT A

PLAINTIFF'S 2/22/16 NOTICE OF CLAIM/93A DEMAND LETTER

ROSS LAW OFFICES, P.C.
Civil Litigation Concentrating in Recovery for Negligence and Wrongful Death
18 East Chestnut Street
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Howard S. Ross, Civil Litigator
Member of the Bar in:
Massachusetts: State and Federal Courts
Rhode Island: State and Federal Courts
Colorado: Federal Court
Pennsylvania: Pro Hac Vice

Website: www.rosslawofficespc.com
E-mail: info@rosslawofficespc.com

February 22, 2016

VIA CERTIFIED MAIL
Howmedica Osteonics Corp
d/b/a Stryker Orthopaedics
325 Corporate Drive
Kalamazoo, MI 49002

Adriana G. Agnihotri
Stryker Legal Department
59 Rt. 17S
Allendale, NJ 07401

Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ 07430

FORMAL NOTICE OF CLAIM AND DEMAND FOR RELIEF PURSUANT TO MASSACHUSETTS GENERAL LAWS, CHAPTER 93A AND MASSACHUSETTS GENERAL LAWS, CHAPTER 106, §§ 2-313, 2-314, 2-315 AND 2-318

Dear Adriana and Sirs/Madams:

Please be advised that I represent Brenda Healy; her husband, Geoffrey Healy; and their three minor children, Kyle, Danielle, and Jeffrey, all of 10 Pilgrim Way, East Walpole, Massachusetts, regarding severe damages they have all sustained as a result of the failure of Stryker products originally implanted in Brenda's right hip on September 16, 2010, products designed, manufactured, promoted, advertised, sold by Stryker and its agents and employees.

The serious injuries sustained by Mrs. Healy and the consequential damages suffered by her family were, and are, the direct result of breaches of implied warranties imposed by law on Stryker for its manufacture, design, advertising, promotion, distribution and/or sale of its products implanted in Brenda Healy. Therefore, this letter correspondence constitutes our formal notice of claim and written demand for relief pursuant to M.G.L. c. 106 §§ 2-313, 2-314, 2-315, 2-318 and M.G.L. c. 93A §2-9. The Healys seek full and fair compensation for the damages they have suffered, and will in the future suffer, as a result.

The Stryker hip replacement products implanted in Mrs. Healy were defective as they did not function safely and, in fact, caused severe metallosis and tissue and muscle death and loss in and around Brenda's hip where the Stryker metal products were implanted; and the defective Stryker products had to be removed due to design and/or manufacturing flaws or defects, thereby requiring the removal on 9/17/15 and replaced with a different hip prosthesis. As a direct and proximate result of Stryker's defective hip prosthesis, Mrs. Healy has suffered immense pain and suffering, emotional distress, further disability, and substantial financial loss and medical expenses. In addition, Brenda's husband and three children have suffered immensely as well, and have suffered as well, and assert loss of consortium claims.

The Consumer Protection Act, Chapter 93A of the Massachusetts General Laws, and the regulations promulgated thereunder by the Attorney General, outlaw conduct and practices by a corporation toward consumers which is deemed unfair or deceptive. The Stryker products implanted in Mrs. Healy did, in fact, breach the warranties that are imposed by Massachusetts law. The Courts have defined unfair and deceptive conduct to include the failure to comply with any law of the Commonwealth, including the laws governing Express and Implied Warranties. In addition, according to Attorney General Regulation 3.08(2), "it shall be an unfair and deceptive act or practice to fail to perform or fulfill any promises or obligations arising under a warranty."

The unfair and deceptive practices of Stryker further consist of breaching the laws governing the Implied Warranties of (1) Merchantability, and (2) Fitness for a particular Purpose. Moreover, Stryker failed to warn patients, as the Stryker products proved to be not reasonably safe or fit for their intended usage and contained unreasonably dangerous design defects causing high levels of toxic metal debris, which caused death of tissue and muscle.

For all of the reasons stated above, Brenda Healy and her husband and three children hereby make demand upon Stryker pursuant to M.G.L. c. 93A in the amount of Two Million Dollars ($2,000,000.00) if Howmedica/Stryker is willing to settle this matter at this time prior to suit being filed.

Massachusetts law, to which the Healy family is entitled to the protection of as Massachusetts residents, provides that Howmedica/Stryker is required to respond to this letter within 30 days. A failure to respond and make a reasonable offer of settlement within 30 days will allow the court to assess multiple damages, up to triple damages, and attorney's fees and costs. It is the intention of my clients to pursue all claims, including but not limited to seeking treble damages and attorney fees, if this matter is not settled, which would necessitate the Healys' filing suit.

I await your reply, and look forward to working with you and your counsel to fairly resolve this matter.

Very truly yours,

Howard S. Ross

HSR/md
Enclosure
cc: Kim Catullo, Esq.
Paul Asfendis, Esq.

EXHIBIT B

DEFENDANT'S 3/17/16 REPLY TO PLAINTIFF'S 2/22/16 NOTICE OF CLAIM/93A DEMAND LETTER

GIBBONS

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March 17, 2016

Via Facsimile and First Class Mail
Howard S. Ross, Esq.
Ross Law Offices, P.C.
18 East Chestnut Street
Sharon, MA 02067

Re: **Brenda Healy and Geoffrey Healy**

Dear Mr. Ross:

We have been retained by Stryker Corporation ("Stryker") and Howmedica Osteonics Corp. (which has done business as "Stryker Orthopaedics") ("HOC") (collectively "Stryker") to respond to your letter purporting to make demands pursuant to Mass. G.L. c. 93A, §9, dated February 22, 2016.[1]

You indicate in your letter that your client, Brenda Healy, claims to have undergone implantation of "Stryker hip replacement products" in September 2010. You claim that implants were defective as they caused metallosis and tissue damage, and that the Stryker implants were removed on September 17, 2015. You allege that Stryker breached warranties and failed to warn patients regarding design defects. You have stated a settlement demand in the amount of $2 million.

As an initial matter, we note that Stryker Corporation does not design, manufacture, test, market, sell or distribute hip systems or components. Thus, your letter to Stryker Corporation's corporate office in Kalamazoo, Michigan, is misdirected.

Regarding the allegations in your letter related to HOC, you have provided incomplete medical records for Ms. Healy, which are insufficient to allow us to assess your claim that Brenda Healy received a defective product, or that the product was an actual and proximate cause of injury. The limited records you have provided reveal that Ms. Healy was implanted with an HOC acetabular cup and insert, however the femoral stem and femoral head do not appear to be HOC product. The revision surgery in September 2015 involved removal of all of the implant components. We note that the revision report indicates that the femoral stem was found to be retroverted at the time of revision.

[1]We have been retained solely for the purpose of responding to your letter and our representation does not constitute an appearance or agreement to waive service of process in connection with any legal proceeding or action.

The evaluation of a claim involving allegations of product defect and deceptive trade practices requires additional information and supporting documentation and materials. While it is difficult to anticipate the specific documents and materials that might exist given only the brief background you have provided, a preliminary list would include the following:

1. The explanted hip components (to be examined non-destructively);
2. Complete records in connection with the implant surgery at issue, as well as any revision surgeries;
3. Complete medical records and progress notes leading up to and post the original September 2010 implant, Ms. Healy's any revisions, and, if applicable, post revision(s), including all of the progress notes and visit records from the orthopaedic surgeon(s) for the primary and revision surgeries for the implant at issue;
4. All x-rays, bone scans, CT scans, etc., for the implant(s) in question, as well as any revision implant(s), including scans/films of the subject hip leading up to the subject implant through and subsequent to revision surgery or surgeries;
5. Complete records pertaining to condition or treatment of the subject hip at any time;
6. Complete records pertaining to Brenda Healy's left hip (to the extent they have not been provided in connection with that prior claim), and bilateral knees, including records pertaining to implant surgeries and post-implant care and treatment;
7. Complete records from Brenda Healy's primary care physician(s) and any other healthcare providers who provided care to Brenda Healy for *any* reason for a period of 15 years up to and including the present;
8. Documentation of any claim for lost wages, medical expenses, loss of consortium and any other damages for which Brenda and Geoffrey Healy seek recovery;
9. If a claim for lost wages or other earnings is being asserted, provide complete income tax records for the period 2007 through 2016;
10. If a claim for lost wages or other earnings is being asserted, provide complete employment records for the period 2007 through 2016;
11. Any additional photographs or video depicting the hip implant, the injuries claimed or supporting the damages sought in your letter;

12. The names and addresses of any witnesses and copies of any witness statements; and

13. Any expert report pertaining to your allegations of defect and/or causation.

To the extent you are aware of additional relevant information or documents that exist, please identify and provide same.

Once the above materials are received from you, we will need a reasonable amount of time to evaluate all of the information provided. Obviously, given the importance and amount of outstanding information and records, we will not be in a position to evaluate Ms. and Mr. Healys' claims and respond substantively by March 23, 2016, and will need a reasonable time after receipt of the records to evaluate and respond to the Healy's settlement demand. Kindly send the requested records to my attention and we will be happy to review and evaluate.

Very truly yours,

Paul E. Asfendis